08/909,879

UNITED ST. 3 DEPARTMENT OF COMMERCE
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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/909,879	08/12/97	PRIEELS	J 04012.0188

EXAMINER	
SMITH, L	
ART UNIT	PAPER NUMBER
1818	25

18N2/1124

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DATE MAILED: 11/24/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 19-32 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 19-32 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.
☒ received in Application No. (Series Code/Serial Number) 08/356,372.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

★ U.S. GPO: 1998-421-632/40206

1. This application is a continuation of serial number 08/442,288 which is now abandoned. The examiner assumes that prosecution is carried over to continuation of the present application since there was no amendment indicating otherwise. In view of this, the office action is directed to the merits of claims 19-32 (see 1062 TMOG, volume 137, 1986).

2. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1818.

3. The examiner acknowledges the preliminary amendment adding claims 19-32. Claims canceled are claims 1-18.

4. Claims 19-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to a vaccine composition comprising antigens from Herpes Simplex Virus or the CS protein of plasmodium species or the Hepatitis B surface antigen in combination with adjuvants QS-21 and 3-DMPL and methods of enhancing the immune response, stimulating gamma interferon production and synergistically enhancing the immune response, does not reasonably provide enablement for a vaccine comprising antigens from HIV or FIV. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are drawn to a vaccine composition comprising HIV or FIV antigens and methods. The specification provides no guidance and teaching to enable a vaccine, particularly against HIV. The examiner is interpreting vaccine to indicate protection from disease. The specification provides

no probative evidence to support the claims to a vaccine which would protect humans against AIDS. The obstacles to vaccine development and therapeutic approaches with regard to retroviruses associated with AIDS in humans are well documented in the literature. These obstacles include: 1) the extensive genomic diversity associated with the HIV retrovirus, particularly with respect to the gene encoding the envelope protein, 2) the fact that the modes of viral transmission include virus-infected mononuclear cells, which pass the infecting virus to other cells in a covert form, as well as via free virus transmission, 3) existence of a latent form of the virus, 4) the ability of the retrovirus to "hide" in the central nervous system where blood cells and neutralizing agents carried by the blood cannot reach the retrovirus, due to the blood-brain barrier and 5) the complexity and variation of the elaboration of the disease. The existence of these obstacles establish that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any vaccine or any immunization treatment or any therapeutic regimen on its face. In order to enable claims with regard to drugs and their uses, either in vivo or in vitro data, or a combination of these can be used. However, the data must be such as to convince one of ordinary skill in the art that the proposed claims are sufficiently enabled. When the claims are directed to humans adequate animal data would be acceptable in those instances wherein one of ordinary skill in the art would accept the correlation to humans. Thus in order to rely on animal data there must exist an art-recognized animal model for testing purposes. See In re Hartop, 311 F.2d 249, 135 USPQ 419 (CCPA 1962). With respect to the AIDS-associated retroviruses the art does not recognize any animal model as exhibiting a direct correlation to human disease (see for example Haynes, Science, vol. 260, 1993, pages 1280, copy

enclosed). To date the chimpanzee is the best available animal model for the study of AIDS in humans because it is the only one capable of infection with the HIV or HTLV III/LAV virus. The chimpanzee however, does not develop the full blown syndrome of AIDS, the significance of this failure being the inability to assess challenge after treatment with the purported vaccine. By definition vaccines must not only induce an immune response, but must be immunogenic to the extent that upon subsequent challenge with the live virus, development of the disease is prevented, or better yet infectivity does not occur.

The specification is drawn to enhancing cytolytic responses as well as generating gamma interferon production. However, there appears to be no correlation between these responses and protection from HIV infection. For example, applicant is directed to the study of Butini, et al (already of record) in which it was demonstrated that the existence of high CTL activity in humans with HIV was not predictive of protection or slowing of disease progression. Indeed, Fox has reported (Biotechnology, vol. 12, page 128, 1994, copy enclosed) concerning reports from the First National Conference on Human Retroviruses and Related Infections, that despite some positive results concerning the fight for HIV vaccines and treatment therapies, "AIDS researchers inevitably come back to the conference's central theme. No therapy has emerged as a sure winner in the campaign against HIV, not a preventive vaccine nor a therapeutic vaccine nor any of the immune-system-boosting treatments.".

Additionally, the specification teaches the administration of HSV, CS or Hepatitis antigenic compositions to mice to generate immune responses. The specification fails to provide guidance and

teaching as to doses effective in generating responses to a "feline" virus in mice. It would appear that mice do not become infected with FIV. Therefore, it is not clear how one would reasonably extrapolate from "felines" to mice and it would be difficult to know what doses of these antigens would be effective given a lack of correlation between the two species. In view of all of the above and in view of that which is well known in the art, it is determined that the specification is not commensurate in scope with the claimed subject matter.

5. Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Lynette F. Smith, Art Unit 1818 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1818 FAX telephone number is (703)-305-7939. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lynette F. Smith whose telephone number is (703) 308-3909.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald E. Adams, can be reached on (703) 308-0570.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SMITH/lfs
November 20, 1997

L. F. Smith

LYNETTE F. SMITH
PRIMARY EXAMINER
GROUP 1800